CASE 33515P1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
PATEL ET AL.
APPLICATION NO: 10/743,367
FILED: DECEMBER 22, 2003
FOR: EXTENDED RELEASE ANTIBIOTIC COMPOSITION

Art Unit: 1615

DECLARATION UNDER 37 C.F.R. § 1.131

We, Mahendra R. Patel, Bhaskarbhai C. Patel, and Amol Singh Matharu, make the following declaration in connection with the above-identified application.

1. We are co-inventors of the invention claimed in the above-identified patent application.

2. I, Mahendra R. Patel, am a citizen of the United States of America, residing at 5 Belair Ct., Milltown, NJ 08850. From 1999 to 2004, I was employed by Sandoz in the Research and Development Department located in Dayton, NJ, as Chief Scientific Officer. I left Sandoz in 2004, and I am currently self-employed.

3. I, Bhaskarbhai C. Patel, am a citizen of India, residing at 13 Boxwood Circle, Edison, NJ 08820. From 1999 to 2006, I was employed by Sandoz in the Research and Development Department located in Dayton, NJ, as a Research Scientist. I left Sandoz in 2006 to join Reliant Pharmaceuticals, located in Liberty Corner, NJ, where I am currently employed.

4. I, Amol Singh Matharu, am a citizen of the United States of America, residing at 507 Timberbrook Dr. Bedminster, NJ 07921. From 1999 to 2002, I was employed by Sandoz in the Research and Development Department located in Dayton, NJ, as a Research Scientist. I left Sandoz in 2002 to Novartis Pharmaceuticals, located in East Hanover, NJ, as a Principal Scientist/Project Leader, where I am currently employed.

5. We have read page 2, lines 2 to 11, of the Office Action from the U.S. Patent and Trademark Office, dated March 29, 2007.

6. We conceived and reduced to practice the invention claimed in the above-identified patent application in the Research and Development Department of Sandoz located in Dayton, NJ, prior to June 16, 2003, which is the 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2005/0064034 (Li et al.), as evidenced by the report titled "Request for Patent Clearance of Pre-Biostudy Formulation", a copy of which is attached hereto as Exhibit 1 with the dates removed. Applicants' report shows a pharmaceutical composition containing clarithromcycin and hydroxyproplymethyl cellulose 2910, viscosity E5LV and hydroxypropylmethyl cellulose 2910, viscosity E15LV. Thus, applicants conceived and reduced to practice one embodiment of the invention as claimed in the above-identified patent application prior to June 16, 2003, which is the 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2004/0064034.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

_____
Mahendra R. Patel

Date:

_____
Bhaskarbhai C. Patel

Date:

_____
Amol Singh Matharu

Date: 10-JULY-2007

Exhibit 1

Send to Linda Adams, Corporate Intellectual Property, East Hanover, Fax No. 862-778-8064

No. 26

GENEVA PRODUCT DEVELOPMENT

REQUEST FOR PATENT CLEARANCE OF PRE-BIOSTUDY FORMULATION

SECTION I. (to be completed by GPTC Development)

Active Ingredient: Clarithromycin

Dosage Form & Strength: ER Tablet 500 mg

Reference Product: Biaxin XL (Abbott)

Submitter: Bhaskar Patel

Date:

SECTION II. (to be completed by GPTC Development)

Pre-Biostudy Formulation:

Ingredient	Percent Composition by Weight (%)	Amount per Tablet (mg)
CORE TABLET		
Clarithromycin	40.85	500.000
Hydroxypropylmethyl Cellulose 2910 (viscosity E5LV)	38.71	470.000
Hydroxypropylmethyl Cellulose 2910 (viscosity E15LV)	16.47	200.000
Magnesium Stearate	1.23	15.000

Syloid-244 (Silicon Dioxide)	0.41	5.000
COATING		
Hydroxypropylmethyl Cellulose 2910 (viscosity E5LV)	1.14	14.000
Hydroxypropylmethyl Cellulose 2910 (viscosity E15LV)	0.49	6.000
Titanium Dioxide	0.16	2.000
Polyethylene Glycol 3350	0.16	2.000
Purified Water	N/A	q. s.
Total Hydroxypropylmethyl Cellulose 2910	**56.84**	**690**
TOTAL	100%	1214.000

SECTION III. (to be completed by patent attorney)

Patent(s) Considered: _____

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SECTION IV. Patent Department Recommendation

Approved:_____ Not Approved _____

Active Ingredient:_____

Dosage Form & Strength:_____

Attorney:_____ Date:_____

Comments:_____

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Original: Patent Department files
Copy 1: Submitter
Copy 2: P. Davila (GPTC, Dayton)